

Notice of Allowability

Application No.

09/502,498

Examiner

Malgorzata A. Walicka

Applicant(s)

KILIAN ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment of March 22, 2004.
2. ☒ The allowed claim(s) is/are 18, 19 and 67-71.
3. ☒ The drawings filed on 22 March 2004 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

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The Amendment filed on March 22, 2004, comprising amendments to the claims, drawings and substitute specification, is acknowledged. The formal drawings are acknowledged. Amendments have been entered as requested. Claims 1-17 and 20-66 are cancelled. Claims 18, 19, 67, 69 and 70 are currently amended. New claim 71 is entered. Claims 18-19 and 67-71 are the subject of this Office Action.

Detailed Office Action

1. Objections

1.1. Specification

The objections to the specification made in the Office Action of Jan. 20, 2004 are withdrawn because the required substitute specification has been filed.

1.2 Drawings

The objections to drawings made in the Office Action of Jan. 20, 2004 are withdrawn because the required changes has been entered to Fig. 11A and 11L.

1.3 Claims

Objection to claim 19 as being dependent on rejected claim 18 is withdrawn because the base claim has been amended.

An objection to claim 70 is withdrawn because the claim has been amended as suggested.

2. Rejections

2.1. 35 U.S.C. 112, second paragraph

Rejection of claim 70 made in the Office Action of Jan. 20, 2004 is withdrawn, because the claim has been amended.

2.2. 35 U.S.C. 112, first paragraph

Rejection of claim 16 maintained in the Office Action of Jan. 20, 2004 now moot because the claim has been cancelled.

Rejection of claim 69 made the Office Action of Jan. 20, 20 is withdrawn, because the claim has been amended.

2.3. 35 USC section 102

Rejection of claim 18 maintained in the Office Action of Jan. 20, 2004 is withdrawn, because the claim has been amended by cancellation of SEQ ID NO: 35.

3. Examiner's amendment

Please amend the claims as follows:

In claim 68 – cancel “35” immediately after “SEQ ID Nos.” in the second line.

In claim 70 – cancel unnecessary period after “SEQ ID No: 2,” in the fourth line;

- replace “.” with “,” after “SEQ ID No: 1” in the fifteenth line.

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Authorization for this examiner's amendment was given by Applicants' representative Carol Nottenburg on April 9, 2004.

4. Allowance

Claims 18-19 and 67-71 are allowed. The following is the examiner's reason for allowance.

Applicants disclose novel splice variants of human telomerase of SEQ ID NOs: 35, 37, 39, 42, 44, 46, 48, 50, 52-54, 56-58, 60-62, 64-66, 68-70, 72-74, 76-78, 80-82, and 84-86. Said novel splice variants result from splicing in/out of the novel alternative intronic/exonic sequences having polynucleotide sequences of SEQ ID Nos: 23, 25, 27, 29, 30, 32, and 33.

The claimed invention is novel and not obvious over the prior art, the closest of which is US Patent No. 6,093, 809, effective filing date May 6, 1997, issued to Cech et al. The patent discloses one splice variant of human telomerase reverse transcriptase (SEQ ID NO: 225, encoded by SEQ ID NO: 224), which is identical to SEQ ID NO: 2 of the instant application and used by Applicant as a reference amino acid sequence. The patent does not suggest the alternative intronic-exonic sequences disclosed for the first time by Applicants. While the polypeptide sequences encoded by the polynucleotide sequences identified by SEQ ID NOS: 25 and 27 are encompassed within the telomerase disclosed by Cech et al., there is nothing in the Cech et al. patent to suggest these sequences are alternative exon/intron fragments specifically. The disclosure of a large genus (in this case fragments of telomerase gene of SEQ ID NO: 224 or peptide

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fragments of the telomerase of SEQ ID NO: 225 taught by Cech et al.) does not make obvious a specific member thereof (i.e., SEQ ID NOS: 25 or 27 or the peptide enclosed thereby in the instant application) without some teaching leading to that specific member. Nothing in Cech et al. patent or the art as a whole would lead a skilled artisan to the proteins encoded by splicing in and/or out of SEQ ID NOS: 25 or 27 from the primary transcript of the genomic sequence.

The rejections under 112, 1st paragraph are withdrawn in view of the amendments to the claims. As amended Claims 18, 19, and 69-71 are now limited to proteins encoded by nucleic acids produced by the alternative splicing of the human telomerase genomic sequence at the specific splice junctions defined in the specification or specific fragments thereof. Therefore, the splice variant sequences disclosed in the specification are representative of the structures and functions of the genus now claimed. As amended claims 67 and 68 are now limited to a genus of proteins which share structural features (all have at least 90% identity to specific amino acid sequences) and functional features (binding to telomerase RNA or telomerase activity) with the specific proteins disclosed in the specification. As such the specific species disclosed in the specification are representative of the claimed genus.

The invention claimed by Applicants has clinical application in diagnosis and treatment of many diseases related to cancer and aging.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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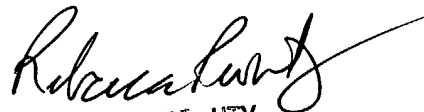
accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (571) 272-0944 and the right fax number is (571) 273-0944. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m. EST.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (571) 272-0928. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.
Art Unit 1652
Patent Examiner


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